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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|------------------------|----------------------|---------------------|------------------|
| 10/766,631 | 01/28/2004 | Zhong Zhang | TPIP018X2 | 3752 |
| 23122 RATNERPRES | 7590 06/12/200 STIA | 8 | EXAMINER | |
| POBOX 980 | CE DA 10492 0090 | | GEMBEH, SHIRLEY V | |
| VALLEY FORGE, PA 19482-0980 | | | ART UNIT | PAPER NUMBER |
| | | | 1618 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 06/12/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | | Application No. | Applicant(s) | | | |
|---|---|---|--|--|--|--|
| | | 10/766,631 | ZHANG ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | SHIRLEY V. GEMBEH | 1618 | | | |
| The MAILING Period for Reply | DATE of this communication app | ears on the cover sheet with the c | orrespondence address | | | |
| WHICHEVER IS LON - Extensions of time may be after SIX (6) MONTHS fron - If NO period for reply is spe - Failure to reply within the s Any reply received by the C | NGER, FROM THE MAILING DA available under the provisions of 37 CFR 1.13 in the mailing date of this communication. ecified above, the maximum statutory period we et or extended period for reply will, by statute, | IS SET TO EXPIRE 3 MONTH() ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be time 17 rill apply and will expire SIX (6) MONTHS from 18 cause the application to become ABANDONE 18 date of this communication, even if timely filed | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | | | | | | |
| 1) Responsive to | communication(s) filed on 26 Ma | arch 2008 | | | | |
| 2a)⊠ This action is F | , , | action is non-final. | | | | |
| <i>'</i> — | · | | | | | |
| • | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1,11,12,20,23-37,39-64,66-68 and 71-78</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1,11,12,20,23-37,39-64,66-68 and 71-78</u> is/are rejected. | | | | | | |
| 7) | _is/are objected to. | | | | | |
| 8) Claim(s) | are subject to restriction and/or | election requirement. | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification | on is objected to by the Examine | r. | | | | |
| 10) The drawing(s) | filed on is/are: a) acce | epted or b)□ objected to by the E | Examiner. | | | |
| Applicant may no | ot request that any objection to the | drawing(s) be held in abeyance. See | e 37 CFR 1.85(a). | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C | . § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | and (DTO 902) | (A) □ Index 1 - 0 | (PTO 442) | | | |
| Notice of References Cit Notice of Draftsperson's | red (PTO-892) Patent Drawing Review (PTO-948) | 4) | | | | |
| | statement(s) (PTO-1449 or PTO/SB/08) | | atent Application (PTO-152) | | | |

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DETAILED ACTION

Response to Arguments

The response filed **3/26/08** presents remarks and arguments to the office action mailed **9/12/07**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of claims

Claims 1, 11-12, 20, 23-37, 39-64, 66-68 and 71-78 are pending.

Claims13-19, 21-22, 38, 65 and 69-70 are cancelled.

Claims 1, 37, 49, 66, 71, 75 and 77 are amended.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/26/08, 1/15/08 and 3/26/08 are received and acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 11-12, 20, 23-37, 39-64, 66-68 and 71-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

No where in the specification is there a mention of the aqueous solution including less than 1% lipids as amended.

Claim Rejections - 35 USC § 103

Claims 1, 11-12, 20, 23-37, 39-64 and 71-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glen et al US 4,452,817 taken with Meadow et al., WO 03/017977 A1 (of record) in view of May et al., US 6,140,374 (of record) and Lee et al., US 6,743,436 B1 (of record).

Claims 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glen et al US 4,452,817 in view of Meadow et al., WO 03/017977 A1 as applied to claims 49-64, 66-68 and 71-74 above, and further in view of May et al., US 6,140,374 and Lee et al., US 6,743,436 BI. (of record)

Applicant argued in generality to the above rejections.

Applicant alleges that Glenn is relied upon by the office for its description of a propofol comprising 10% PEG 200 and 10% cremophor in that the claimed invention is

distinguishable by having less than 1% lipid. Also Applicant argues that the excipient is less than 15%.

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In response, Glenn teaches a lipid free propofol that does not contain a surfactant, see col. 2, lines 54-60 and examples 10(a) for example, does not comprise oil. With regard to the excipient being less than 15% is also taught by Glenn. For example col. 5, lines 26-30 teaches the excipient as polyoxyethylene monostearate is 5%.

Applicant's arguments filed have been fully considered but they are not persuasive because of the above reason.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/ Supervisory Patent Examiner, Art Unit 1618

SVG 6/4/08